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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,045

08/29/2006

Johannes Auer

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151 7590 10/23/2009
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

10/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,045	Applicant(s) AUER ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/09 has been entered.

Applicant's arguments filed 9/8/09 have been fully considered but they are not persuasive.

Claims 1-6 are under consideration by the examiner.

The rejection of claims 1-6 under rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al. in view of Fuglsang, Olivares-Trejo et al., and Jeh et al. is withdrawn in view of the claim rejections. This rejection could be reapplied if applicant amends the claims to overcome the new matter rejection set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Page 6 of the specification discloses that:

SEQ ID NO:1 Amino acid sequence and DNA sequence encoding the α -chain of HGF, original sequence according to GenBank M73239 (without signal sequence)

SEQ ID NO:2 Protein sequence of the α -chain of HGF

SEQ ID NO:3 Amino acid sequence and DNA sequence encoding NK4 according to the invention (amino acid sequence including N-terminal methionine, DNA sequence including two stop codons)

SEQ ID NO:4 Protein sequence of NK4

Inspection of these sequences shows that SEQ ID NO: 1 corresponds to nucleotides 159-1547 of GenBank M73239 and SEQ ID NO: 2 corresponds to amino acids 32-494 of the encoded sequence. The nucleic acid sequence of SEQ ID NO: 3 encodes an N-terminal methionine, followed by a serine, followed by a sequence encoding amino acids 33-478 as disclosed in Swiss-Prot P14210, followed by two stop codons (taa and tag). The codons for the Arg amino acids at positions 3, 5, and 6 of the encoded sequence are each CGT in SEQ ID NO: 3. SEQ ID NO: 4 corresponds to Met, Ser, followed by amino acids 33-478 as disclosed in Swiss-Prot P14210. Note that these ranges of amino acids DO NOT correspond to the numbering in instant SEQ ID NOS: 1-4.

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Thus, the recitation in claim 1 as amended “amino acids 32-207 of SEQ ID NO: 3” is not disclosed by the specification. The amino acid positions in the specification are with respect Swiss-Prot P14210. (See page 2 of the specification.) The only place the specification references any sequence identifiers is on page 6. Similarly, the recitation in claim 5 as amended “amino acids 32-207 of SEQ ID NO: 2” is not disclosed by the specification. It appears that amino acids 3-177 of SEQ ID NO: 4 correspond to amino acids 33-207 of Swiss-Prot P14210. It appears that amino acids 3-448 of SEQ ID NO: 4 correspond to amino acids 33-478 of Swiss-Prot P14210. It appears that nucleotides 1-531 of SEQ ID NO: 3 encode amino acids 1-177 of SEQ ID NO: 4. It appears that nucleotides 1-1344 of SEQ ID NO: 3 encode amino acid acids 1-448 of SEQ ID NO: 4. Applicant is reminded that the serine at amino acid position 2 of SEQ ID NO: 4 reflects the amino acid substitution of serine for glutamine at amino acid position 32 of Swiss-Prot P1420. (See paragraph bridging pages 2-3 of the specification.)

The following claims would be allowable.

1. A nucleic acid comprising nucleotides 1-531 of SEQ ID NO: 3.
2. A nucleic acid comprising nucleotides 1-1344 of SEQ ID NO: 3.
3. A nucleic acid encoding amino acids 1-177 of SEQ ID NO: 4 wherein at least one of the codons encoding Arg at amino acid positions 3, 5, and 6 of SEQ ID NO: 4 is CGT.
4. The nucleic acid of claim 4 wherein each of the codons encoding Arg at amino acid positions 3, 5, and 6 of SEQ ID NO: 4 is CGT.

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5. A nucleic acid encoding SEQ ID NO: 4 wherein at least one of the codons encoding Arg at amino acid positions 3, 5, and 6 of SEQ ID NO: 4 is CGT.

6. The nucleic acid of claim 6 wherein each of the codons encoding Arg at amino acid positions 3, 5, and 6 of SEQ ID NO: 4 is CGT.

7. A method for the production of an NK polypeptide comprising the α -chain of hepatocyte growth factor polypeptide or an N-terminal fragment thereof comprising the steps of

- a) expressing the nucleic acid of any one of claims 1-6 in a microbial host cell;
- b) isolating inclusion bodies containing said NK polypeptide in denatured form;
- c) solubilizing the inclusion bodies; and
- d) renaturing the denatured NK polypeptide.

The prior art of record does not disclose nor suggest a nucleic acid encoding an NK polypeptide having Met-Ser at the N-terminus in combination with the specific CGT codons for arginine at positions 3, 5, and/or 6 of SEQ ID NO: 4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa